Synlogic Announces Clinical Collaboration to Evaluate SYNB1891 in Combination with PD-L1 Checkpoint Inhibitor in Patients with Advanced Solid Tumors

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 22, 2019-- Synlogic, Inc., (Nasdaq: SYBX) a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, today announced a new clinical collaboration with Roche (SIX:RO, ROG), to explore Synlogic's Synthetic Biotic™ medicine, SYNB1891, a dual innate immune activator engineered to express a STING agonist, in combination with Roche's PD-L1-blocking checkpoint inhibitor (CPI) atezolizumab (Tecentriq®) in patients with advanced solid tumors. Synlogic expects to file an Investigational New Drug (IND) application with the U.S. Federal Drug Administration (FDA) in the second half of 2019 for SYNB1891 to enable the company to begin an open-label Phase 1 clinical trial to evaluate the candidate as a monotherapy and a combination treatment with atezolizumab.

"This collaboration is an important step in advancing SYNB1891 as a potential treatment for difficult to treat cancers as it provides us with access to an important checkpoint inhibitor, atezolizumab, while allowing us to maintain ownership of our novel development candidate," said Aoife Brennan, M.B. Ch.B., Synlogic's president and chief executive officer. "We believe that SYNB1891 has potential to offer a new and meaningful approach in the fight against cancer when used in combination with checkpoint inhibitors, by potentially enhancing their potency and effectiveness."

Tumors have developed mechanisms to subvert natural processes to suppress and evade immune control. While the use of CPIs has greatly improved outcomes for patients with certain types of cancers, a percentage of patients still do not respond to these therapies. Engagement of both the innate and adaptive arms of the immune system has been shown to be critical in generating an efficacious antitumor immune response.

SYNB1891 is a non-pathogenic strain of *E.coli* that has been engineered to express a STING (STimulator of INterferon Genes) agonist and stimulate the innate immune system. When the bacteria are engulfed by antigen presenting cells within the tumor, the STING pathway is activated within the cell resulting in a type I interferon (IFN) response and the initiation and propagation of tumor-specific T-cell responses. In addition, the bacterial chassis used in Synlogic's Synthetic Biotic approach is believed to stimulate the innate immune system by several other mechanisms, including via Toll-like receptors, potentially adding to the magnitude of the overall immune response. In combination with atezolizumab, SYNB1891 has the potential to elicit both innate and adaptive arms of the immune system to drive tumor reduction.

With an active IND, Synlogic plans to initiate an open-label, multicenter Phase 1 clinical trial of SYNB1891 administered by intra-tumoral (i.t.) injection to patients with advanced/metastatic solid tumors. The primary objective of the study is to evaluate the safety and tolerability of escalating doses of SYNB1891 to determine the single-agent maximum tolerated dose (MTD) as monotherapy and the recommended Phase 2 dose in combination with atezolizumab. In addition, the study will explore immune biomarkers, objective response rates (ORR), and time to progression for evaluated tumors. Synlogic will be the sponsor of the study and Roche will provide clinical supply of atezolizumab.

About Synlogic
Synlogic is pioneering the development of a novel class of living medicines, Synthetic Biotic medicines, based on its proprietary drug development platform. Synlogic leverages the tools and principles of synthetic biology to genetically engineer beneficial microbes to perform or deliver critical functions missing or damaged due to disease. Synthetic Biotic medicines are designed to act locally and have a systemic effect to address disease in patients. Synlogic's two lead programs, SYNB1020 and SYNB1618, are orally administered and target hyperammonemia as a result of liver damage or genetic disease, and phenylketonuria, respectively. Synlogic is also developing SYNB1891 as an intratumorally-administered Synthetic Biotic medicine for the treatment of cancer. In addition, the Company is leveraging the broad potential of its platform to create additional Synthetic Biotic medicines for the treatment of liver disease, as well as inflammatory and immune disorders including Synlogic's collaboration with AbbVie to develop Synthetic Biotic-based treatments for inflammatory bowel disease (IBD). For more information, please visit www.synlogictx.com.

Tecentriq® is a registered trademark of Hoffman-La Roche Ltd.

Forward-Looking Statements
This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Synlogic may identify forward-looking statements. Examples of forward-looking statements, include, but are not limited to, statements regarding the potential of Synlogic's platform to develop therapeutics to address a wide range of diseases including: inborn errors of metabolism, liver disease, inflammatory and immune disorders, and cancer; the future clinical development of Synthetic Biotic medicines; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; the potential of Synlogic's technology to treat hyperammonemia, phenylketonuria and cancer. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including: the uncertainties inherent in the preclinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Synlogic's filings with the SEC. The forward-looking statements contained in this press release reflect Synlogic's current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic's view as of any date subsequent to the date hereof.

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